UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/632,537	08/01/2003	Paul V. Goode JR.	DEXCOM.024A	2669

20995 7590 10/20/2004

KNOBBE MARTENS OLSON & BEAR LLP
2040 MAIN STREET
FOURTEENTH FLOOR
IRVINE, CA 92614

EXAMINER	
NGHIEM, MICHAEL P	

ART UNIT	PAPER NUMBER
2863	

DATE MAILED: 10/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/632,537	GOODE ET AL.	
	Examiner	Art Unit	
	Michael P Nghiem	2863	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-33* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *29,31 and 32* is/are allowed.

6)☒ Claim(s) *1-5,10-14,19-23,28,30 and 33* is/are rejected.

7)☒ Claim(s) *6-9,15-18 and 24-27* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *01 August 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Objections

1. Claims 10, 20, and 21 are objected to because of the following informalities:

- claim 10, "method" (line 2) should be – system --.

- claim 20, "the user interface" (line 2) lacks antecedent basis.

- claim 21, "the user" (line 2) lacks antecedent basis.

Appropriate correction is required.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-5, 10-14, 19-23, 28, 30, and 33 are rejected under 35 U.S.C. 102(b) as being anticipated by Gross et al. (US 6,275,717).

Regarding claims 1, 10, 19, 28, 30, and 33, Gross et al. discloses a method and system (Fig. 1a) for evaluating clinical acceptability of at least one of reference and sensor analyte data, comprising:

- receiving a data stream (further sensor signals, lines 48-50, received from 15) from an analyte sensor (15), including one or more sensor data points (further sensor signals);

- receiving reference data (first sensor signal, column 19, line 44) from a reference analyte monitor (from 15 of monitor device 10), including one or more reference data points (first sensor signal);

- evaluating the clinical acceptability at least one of said reference and sensor analyte data using substantially time corresponding reference or sensor data (column 19, lines 45-50), wherein said at least one of said reference and sensor analyte data is evaluated for deviation from its substantially time corresponding reference or sensor data (column 19, lines 10-13) and clinical risk (analyte level passes beyond limit, column 19, lines 12-13) associated with that deviation based on the glucose value indicated by at least one of said sensor and reference data (glucose levels too high, column 10, line 6).

Regarding claims 2, 11, 20, 28, and 30, Gross et al. further discloses providing an output (via controller, column 19, line 14through a user interface (24 displays data/levels to user) responsive to said clinical acceptability evaluation.

Regarding claims 3, 12, and 21, Gross et al. discloses that the step of providing an output includes alerting the user based on said clinical acceptability evaluation (column 19, lines 16-18).

Regarding claims 4, 13, and 22, Gross et al. discloses that the step of providing an output includes altering the user interface based on said clinical acceptability evaluation (changes display to display warning if analyte level is beyond limit, column 19, lines 13-18).

Regarding claims 5, 14, 23, and 33, Gross et al. further discloses that the step of altering the user interface includes at least one of providing color-coded information, trend information, directional information, and fail-safe information (warning information).

Allowable Subject Matter

3. Claims 6-9, 15-18, and 24-27 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

4. Claims 29, 31, and 32 are allowed.

Reasons For Allowance

5. The combination or method as claimed wherein evaluating the clinical acceptability includes using one of a Clarke Error Grid, a mean absolute difference calculation, a rate of change calculation, a consensus grid, and a standard clinical acceptance test (claims 6, 15, 24, 29, 31, 32) or requesting additional reference data if said clinical acceptability evaluation determines clinical unacceptability (claims 7, 16, 25) or matching reference data to substantially time corresponding sensor data to form a matched pair after the clinical acceptability evaluation step (claims 9, 18, 27) is not disclosed, suggested, or made obvious by the prior art of record.

Conclusion

6. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Say et al. (US 6,175,752) discloses an analyte monitoring device (Fig. 1).

Contact Information

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Nghiem whose telephone number is (571) 272-2277. The examiner can normally be reached on M-H from 6:30AM – 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John Barlow can be reached at (571) 272-2269. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0956.

MICHAEL NGHIEM
PRIMARY EXAMINER

Michael Nghiem

October 14, 2004